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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,879	03/18/2004	Sergio Abrignani	2300-0336.10	7660

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT PAPER NUMBER

1648

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,879

Applicant(s)

ABRIGNANI, SERGIO

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 24-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 18 and 24-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Currently, claims 18, and 24-32 are pending and under consideration. In the prior action, mailed on November 17, 2004, claims 18 and 21-23 were pending and rejected. In the Response, filed on March 17, 2005, the Applicant amended claim 18; cancelled claims 21-23, and added new claims 24-32.

Claim Rejections - 35 USC § 101

2. **(Prior Rejection- Withdrawn)** Claims 18 and 21-23 were rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility. In view of the amendment of the claims in the application, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(Prior Rejection- Maintained)** Claims 18 and 21-23 were rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is a method indicating how the ability to bind to the 24kd protein relates to the compounds ability to bind to HCV. The Applicant has amended claim 18, and drafted claims 24-27, to read on methods for the

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identification of compounds that compete with HCV binding to the 24 kd protein. Additionally, the Applicant has added new claims 28-32 which read on the identification of mimics to the HCV surface structure that binds the 24 kd protein. However, while the claims provide for a step of measuring the binding of the compound to the 24 kd protein, the claims do not provide for a step associating the results of such measurement to the ability of the compound to compete with HCV, or for identification of the compound as a mimic. It is suggested that the claims add a further step noting that binding of the compound to the 24 kd protein indicates the compound as a competitor or mimic.

5. **(New Rejection-Necessitated by Amendment)** Claims 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims read on methods for the identification of “chemical compounds that mimic the HCV surface structure that binds to the HCV receptor.” It is not clear what is meant by this phrase. It is unclear if the claims are directed to the identification of compounds that structurally mimic the HCV structure, or if the claims require the identification of compounds that mimic the HCV structure only in that they also bind to the 24 kd protein. Because it is unclear what is meant by the phrase “chemical compounds that mimic the HCV surface structure that binds to the HCV receptor,” the claim is rejected as indefinite.

Clarification is required.

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6. **(New Rejection-Necessitated by Amendment)** Claims 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims refer methods of screening for mimics of the HCV structure that binds to “the HCV receptor.” However, while the application has identified a putative HCV receptor, the application has not demonstrated that this is the sole HCV receptor. Further, the art teaches that HCV also binds to other cell surface structures, and indicates that these other structures also act as HCV receptors. See e.g., Germi et al., J Med Virol 68: 206-15, at page 206. Because the present application neither identifies a receptor as the sole HCV receptor, and because the art indicates that there are more than one HCV receptors, it is not clear what is meant by the phrase “the HCV receptor.”

Clarification is required.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **(Prior Rejection- Maintained)** Claims 18 and 21-23 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being (for the purposes of this rejection) enabling for the claimed methods wherein the protein to which binding is being screened is the 24kd protein that binds to the HCV E2 protein, does not reasonably provide enablement for methods using any “functionally equivalent” or fragment thereof. The rejection is withdrawn from claim 21-23 as moot because the claims have been cancelled. However, the rejection is

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extended to new claim 28. Because the other new claims require that a process that would result in the full-length protein produces the protein, the rejection is not extended to these claims. The Applicant has amended claim 18, and drafted claim 28, to refer to truncated proteins instead of to functionally equivalent fragments. The Applicant asserts that the amendment has overcome the rejection. However, as the claims still read on the use of fragments of the 24 kd protein, and as they have presented no support for the use of such fragments (e.g. through the identification of structures required for HCV binding to the protein), the amendment is not found sufficient to overcome the rejection.

Further, while the Applicant asserts that the specification provides adequate information to enable the claims, and asserts that the burden is on the Office to explain its reasons for rejection, the Applicant has provided no more than unsupported assertions of their position in response to the rejection. Because the Applicant has not provided any evidence to show enablement in contrast to the reasons presented by the Office in the prior action, the Applicant's arguments are not found persuasive. The rejection is therefore maintained for the reasons above, and the reasons of record.

9. **(Prior Rejection- Maintained)** Claims 18 and 21-23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claim 18 has been amended to further require that the protein is stable to acetone precipitation. Claims 21-23 have been cancelled, and new claims 24-32 have been added. The rejection is withdrawn from claims 21-23 as moot. However, the rejection is maintained against claim 18, and extended to new

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claims 24-25, and 28-30. These claims read on methods of using 24 kd protein from mammalian cells, or mammalian cells which hyperexpresses the 24 kd protein.

The Applicant has presented no additional arguments in traversal of this rejection to those presented with respect to the enablement rejection, and the amendments to the claims. While the Applicant has added an additional functional limitation to the claims, the amendment does not overcome the rejection.

First, the claims now read on truncated forms of the protein that lack a “functional portion of a transmembrane domain.” This amendment does not clarify the structure of the protein that is required for E2 binding. Because the application does not provide any structural identification of the truncated proteins that may be used, the rejection is maintained.

Second, the claims still read on 24 kd proteins from any mammalian cells. However, as indicated in the prior action, the application provides support for the isolation and use only of 24 kd proteins from humans and chimpanzees, and not from any mammal. The additional functional limitations provides an insufficient grounds on which to base claims to methods using 24 kd proteins from other species.

Additionally, newly added claims 25 and 30 read on methods for the isolation of the protein from cells that hyperexpress the protein. However, the application provides no means by which such cells may be identified other than by their functional characteristic of hyperexpression. Further, the application provides only a single example of a cell that hyperexpresses the protein (MOLT-4 cells) and has not provided any non-functional characterization of the cell that correlates with the hyperexpression of the protein. Thus, the application does not provide adequate support for claims drawn to methods of isolating the

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protein from any cell that hyperexpresses it, because there is insufficient support for that genus of cells.

For the reasons above, and the reasons of record, the rejection is maintained.

10. **(New Rejection-Necessitated by Amendment)** Claims 18 and 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of identifying compounds that bind to the 24 kd protein, does not reasonably provide enablement for methods of identifying compounds that compete with HCV for binding to any host cell receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As indicated, the claims are drawn to methods of identifying compounds that “compete with hepatitis C virus for binding to a host cell receptor” comprising the identification of compounds that bind to the 24 kd protein.

The claims are rejected on two basis. First, the claims would identify only compounds that bind to the 24 kd protein, and not compounds that bind any cell receptor. Second, the claims have provided a method for the identification of compounds that bind to the 24 kd protein, but have not provided a means for determining if such compounds would also compete with HCV for binding to the protein. There is no indication that any compound that binds to the 24 kd protein would necessarily compete with HCV binding to the same protein. Additionally, there are no teachings in the application as to which portions of the 24 kd protein are actually targeted by HCV such that those in the art would be able to determine if a compound identified by the

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claimed method binds to the same, or an overlapping region of the 24 kd protein such that it would compete with HCV binding.

In view of the lack of any means provided in the claim for the determination as to whether the compound that binds to the 24 kd protein would also compete with HCV, the Applicant has not enabled the use of the method as claimed to identify such competitors to HCV binding.

11. **(New Rejection-Necessitated by Amendment)** Claims 28-32 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims read on methods for the identification of “chemical compounds that mimic the HCV surface structure that binds to the HCV receptor.” As indicated above, it is not clear what is meant by this phrase. However, because the claims refer to the “HCV surface structure,” the claim is read, for the purposes of this rejection, as though the claim was directed to the identification of compounds that structurally mimic the HCV surface structure- i.e. the HCV E2 protein.

The factors to be considered in making an enablement determination have been described in the prior action. Those factors deemed relevant to the present rejection are the breadth of the claims, the guidance presented in the application, the presence of working examples, and the nature of the invention.

As indicated above, the claims read on methods for the identification of structural mimics of the HCV surface structure that binds to the 24 kd protein. Because the claims read on the identification of "chemical compounds" that mimic the HCV structure, it claims appear to broadly read on any compound that mimics either the HCV E2 protein as a whole, or a portion thereof responsible for the binding of the protein to the 24 kd receptor. However, while the application indicates that the isolated 24 kd protein may be used in such methods, there is no description in the application of such methods, and no identification of any such mimics. Nor is there any identification in the application as to what portion or portions of the HCV E2 protein are actually capable of binding to the 24 kd protein. Thus, other than suggesting the use of the 24 kd protein to identify such mimics, the application provides no additional guidance or information regarding such a use. Because there is no identification of the structures that are to be mimicked, the application has not enabled the identification of such mimics.

Further, even if the application had provided such information, in order to identify such mimics, the methods of identifying such would require at least one additional step to be enabled. While the claims provide for the identification of compounds that bind to the 24 kd protein, they do not provide any means for the determination if the compounds structurally mimic the HCV structure. I.e., there is no step comparing the structure of the HCV surface structure to the structure of the chemical compound. Absent such a step, the claimed method enables the identification only of compounds that bind to the p24 protein, and not the identification of a structural mimic of the HCV structure.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

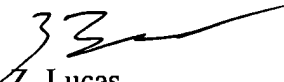
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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